

view of Alfidi. Each of these rejections is respectfully traversed with respect to the claims submitted both before and after this Amendment.

Alfidi discloses a heat-expansible appliance in the form of an internally stressed coil of wire for implantation in a body vessel, with cross-sections of the wire including an elliptical configuration. The only solid form of the appliance (FIGS. 16, 17) is, in expanded form, a completely solid, uninterrupted tube with nothing that might be construed as struts or through-holes as required by applicant's claims. The wire embodiment is composed of nitinol, a memory material, to allow it to be initially formed in a helical coil configuration, subsequently plastically deformed to a straightened wire configuration for insertion into the vessel to be treated, and heated to return to its original (memory) helical coil form (FIGS. 4, 5; col. 5, lines 12-17). Alternatively, a wire embodiment (FIGS. 11, 12; col. 7, line 66 - col. 8, line 10) is initially formed in a large diameter helical coil configuration, plastically deformed to a smaller diameter coil, and then heated to take the larger diameter form.

As a practical matter, the Alfidi appliance in each of its forms presents a multitude of problems, not the least of which is heating it while in the blood stream to a temperature of 330°F (e.g., col. 5, lines 42-53) without serious adverse consequences to the patient's blood, blood flow, and vessel and surrounding tissue. Alfidi says this is "preferably accomplished quickly to prevent damage to surrounding vessel walls and [further,] the blood functions as a cooling medium ..." (col. 3, lines 41-48). With all due respect to the reference, this is no more than wishful thinking. Another problem for Alfidi's wire embodiments is that nitinol tends to straighten rigidly in its unstressed form and to become flexible in its stressed form, which would make for considerable difficulty to create a small diameter form and to insert and navigate a rigid wire in the patient's blood vessel without a high probability of vessel puncture.

That aside, however, as correctly pointed out by examiner Alfidi teaches that "the substantially rectangular and substantially elliptical configurations of FIGS. 13B and 13D are advantageous ... [in] that they maximize the area of contact between the coiled appliance and the wall of the vessel within which the appliance is inserted" (col. 8, lines 13-18). The fact is that prior art stents composed of solid tubular structures that are subsequently machined

(including laser-machining) to provide through-holes (e.g., see applicant's FIGS. 2A and 2B, and related text) were invariably left with rectangular cross-sections, which if anything, is quite in keeping with the "maximizing area of contact" of Alfidi's specification as quoted immediately above. Indeed, the rectangular cross-section offers considerably greater area of contact between the stent and the vessel wall than an oval cross-section, because only the outer portions of the oval's curvature truly contact the wall. Therefore, no reason exists from the teachings of Alfidi for a solid wall open-ended tube with through-holes to be processed such that the portions of the tube between the holes take on an oval shape. Rather, Alfidi's specification teaches against such a modification because the stated desire is to maximize vessel wall contact.

Moreover, although examiner attempts to equate the open space (not multiple spaces, as examiner contends) of Alfidi's helical coil embodiment with applicant's multiplicity of through-holes (claims 61 and , and the winding (not multiple windings, as examiner contends) of that Alfidi embodiment with a plurality of struts bounding the through-holes as claimed by applicant, no basis exists for doing so. And certainly Alfidi discloses nothing that anticipates each of multiple through-holes bounded completely by struts, as recited in claim 65.

Fontaine's stent is a composed of a single filament wire having a series of U-shaped bends, that is wrapped on a mandril to assume a desired configuration for use in a vessel to be treated. It is not a solid wall open-ended tube as clarified in applicant's claims as amended. Further, the portion of Fontaine's specification referred to by examiner, at col. 6, lines 22-26, clearly states a preference for welds at contacting points of the filament. And the only other way to "form the connecting portions of the filament from a single piece of material" to eliminate a need for connecting each of the U-shaped bends, as asserted by Fontaine, is to loop the filament about itself at each of those bends. Otherwise, the wire stent would lose its shape as soon as it was removed from the mandril.

Klein discloses a radially expandable luminal prosthesis in which a pair of body segments is joined by a serpentine ring and two pairs of beam members. Here, also, no reason exists to combine the teachings of Klein with those of Alfidi. The same comments apply as

those set forth above with respect to the attempted combination of Fontaine and Alfidi. Klein is even less relevant than Fontaine in this respect.

Claims 61 and 65 contain limitations, including those that existed prior to this Amendment, and some added or modified by this Amendment, that clearly and patentably define over the references of record. These limitations are discussed above and need not be repeated here. The only other claims remaining in this application are 64 and 68, which depend respectively on base claims 61 and 65.

Claims 62, 63, 66 and 67 have been canceled to dispose of the issue of a method of manufacture contributing to the patentability of a product.

A version of the amended claims marked to show changes made herein is presented in Attachment A to this Amendment.

Early reexamination and allowance of this application are earnestly solicited.

Respectfully submitted,

ECKHARD ALT

By 
Donald R. Greene
Registration No. 22,470
P. O. Box 12995
Scottsdale, AZ 85267-2995
Telephone: (480) 488-4985
Facsimile: (480) 488-5654

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ATTACHMENT A**Version with Markings to Show Changes Made by this Amendment in SN 09/735,401****In the Claims:**

Claims 62, 63, 66 and 67 have been canceled.

Claims 61 and 65 have been amended as follows:

1 -- 61. (Amended) A balloon-expandable vascular or endoluminal stent adapted for
2 deployment in a vessel or tract of a patient to maintain an open lumen therein, comprising a
3 scaffold formed from a single open-ended tube having a solid tubular wall with a multiplicity
4 of through-holes in the tubular wall thereof defined by a plurality of struts bounding said
5 through-holes; each of said struts having an optimized cross-section of oval shape with a short
6 diameter corresponding substantially to the thickness of said wall so that the long sides of the
7 oval lie at the outside or the inside of the tube wall at the respective strut to enhance flexibility
8 of the stent, ease advancement of the stent through a lumen of the vessel or tract for
9 deployment at a target site therein, protect the balloon of a balloon catheter when the stent is
10 tightly crimped thereon, and enhance expansion of the stent during deployment while
11 maintaining its capability to withstand compression in response to recoil of the wall of the
12 vessel or tract following deployment.

1 65. (Amended) A balloon-expandable stent for deployment in a patient's vessel, tract
2 or duct to maintain an open lumen therein, comprising an open-ended elongate tube having
3 a generally circumferential solid wall, a multiplicity of interconnected curvilinear struts
4 formed in the wall of said tube and thereby defining a multiplicity of through-holes in said
5 wall, each of said through-holes being bounded completely by struts; each of said struts having
6 an oval cross-section with a long diameter generally aligned with the length or circumference
7 of said wall and a short diameter generally aligned with corresponding substantially to the
8 thickness of said wall, whereby to enhance the longitudinal flexibility of the stent, ease

9 advancement of the stent through a lumen of the vessel, tract or duct for deployment at a target
10 site therein, protect the balloon of a balloon catheter when the stent is tightly crimped thereon
11 for advancement or expanded therefrom by inflation of the balloon, and enhance expansion
12 of the stent during deployment while maintaining its capability to withstand compression in
13 response to recoil of the wall of the vessel, tract or duct following deployment of the stent as
14 a scaffold in support thereof. —